

## § 890.3850

## 21 CFR Ch. I (4–1–05 Edition)

subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

### § 890.3850 Mechanical wheelchair.

(a) *Identification.* A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class I (general controls).

### § 890.3860 Powered wheelchair.

(a) *Identification.* A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class II (performance standards).

### § 890.3880 Special grade wheelchair.

(a) *Identification.* A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.

(b) *Classification.* Class II (performance standards).

### § 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP for a device de-

scribed in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any stair-climbing wheelchair that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a stair-climbing wheelchair that was in commercial distribution before May 28, 1976. Any other stair-climbing wheelchair shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 52 FR 22577, June 12, 1987; 65 FR 19834, Apr. 13, 2000]

### § 890.3900 Standup wheelchair.

(a) *Identification.* A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.

(b) *Classification.* Class II (performance standards).

### § 890.3910 Wheelchair accessory.

(a) *Identification.* A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.

(b) *Classification.* Class I (general controls). If the device is not intended for use as a protective restraint as defined in § 880.6760 of this chapter, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180,

## Food and Drug Administration, HHS

## § 890.5110

regarding general requirements concerning records, and § 820.198, regarding complaint files.

[61 FR 8439, Mar. 4, 1996, as amended at 66 FR 38817, July 25, 2001]

### § 890.3920 Wheelchair component.

(a) *Identification.* A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

### § 890.3930 Wheelchair elevator.

(a) *Identification.* A wheelchair elevator is a motorized lift device intended for medical purposes to provide a means for a disabled person to move a wheelchair from one level to another.

(b) *Classification.* Class II (performance standards).

### § 890.3940 Wheelchair platform scale.

(a) *Identification.* A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended for medical purposes to weigh a person who is confined to a wheelchair.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning

records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

## Subpart E [Reserved]

## Subpart F—Physical Medicine Therapeutic Devices

### § 890.5050 Daily activity assist device.

(a) *Identification.* A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. If the device is not labeled or otherwise represented as sterile, the device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

### § 890.5100 Immersion hydrobath.

(a) *Identification.* An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(b) *Classification.* Class II (performance standards).

### § 890.5110 Paraffin bath.

(a) *Identification.* A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the